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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,403	05/15/2001	Robert Johnson	A1669cip	9139

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EXAMINER	
DAWSON, GLENN K	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/855,403	JOHNSON ET AL.	
	Examiner	Art Unit	
	Glenn K Dawson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-14,16-18 and 21-31* is/are pending in the application.

4a) Of the above claim(s) *28-31* is/are withdrawn from consideration.

5)☒ Claim(s) *1-9* is/are allowed.

6)☒ Claim(s) *10,12-14,16-18 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Newly submitted claims 28-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the subcombination of the fitting includes limitations of the flexible and rigid ends which are not required in the combination, and the fitting could be used on hose connections for an automobile.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification does not provide antecedent basis for an exhalation filter being in the 3rd port with the medication dispenser, only the 2nd exhalation port.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

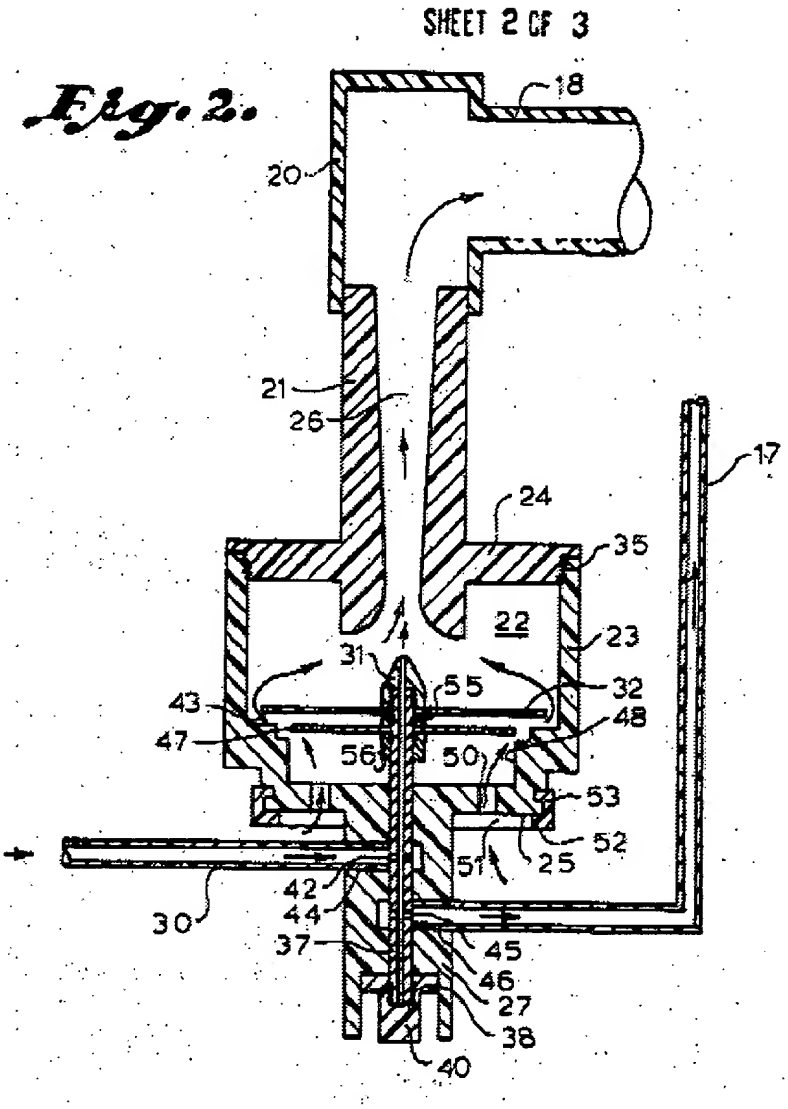
(f) he did not himself invent the subject matter sought to be patented.

Claims 10,12,21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Piper, et al.-5479920.

Piper discloses an aerosol enhancement device having a mouthpiece 54, a spacer including three ports, an inlet port 52, and an adaptor 12 and 18 which comprises a universal fitting which can attach to either a nebulizer 22 or could attach to an MDI. The adaptor could be reversed and attached to an MDI having the same dimension port as that of the nebulizer. Coupling 16 could be removed from 52 and coupling 12 attached to tube 52 while tube 18 could be reattached to 16. See col. 4 lines 15-28 and col. 5 lines 9-16.

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Esbenshade-3769973.

Esbenshade discloses a device having a mouthpiece 12, a spacer member having an inlet port 18 and an adaptor 20 which "could" receive an MDI or a nebulizer.



Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by Watt-6578571.

Watt discloses a mouthpiece 6 attached to a spacer 10 having an inlet port which receives medication from either an MDI or a nebulizer. The medicator is attached to the device by a flexible adaptor, which can be attached to a variety of medicators. A single adaptor can have a plurality of different shaped or sized drug delivery device receiving means including a stretchable adaptor end. Filters can be placed in different locations to filter out exhaled air. A vent having one or more apertures can be used to vent exhalation gas. See col. 1 lines 9-11 and

21-32; col. 4 lines 34-64; col. 5 lines 4-14; col. 6 lines 62-64; col. 7 lines 17-24 and 40-65; col. 8 lines 35-45; col. 9 lines 51,52 and 64-66; col. 10 lines 34-36; col. 11 lines 9-11; col. 12 lines 4-18; col. 14 lines 16-23; col. 16 lines 58-60; col. 17 lines 6-8; col. 18 lines 3-6; col. 19 lines 18-21; and col. 22 lines 17-18.

Claims 14 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Salter, et al.-WO 00/27455.

Salter discloses a device having a mouthpiece attached to a spacer having a 1st port 14 for, a 2nd port 22 having an exhalation filter 47, a flap valve 26 and a valve seat 20 for exhaling gas to be released to the atmosphere, and a 3rd port 12 for attachment to a nebulizer.

Claim 14 is rejected under 35 U.S.C. 102(e) as being anticipated by Salter, et al.-6176234.

Salter discloses a device having a mouthpiece attached to a spacer having a 1st port 14 for, a 2nd port 22 having a flap valve 26 and a valve seat 20 for exhaling gas to be released to the atmosphere, and a 3rd port 12 for attachment to a nebulizer.

Claims 10,12,13,21 and 24-27 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

U.S. Patent No. 6,363,932 discloses the same subject matter claimed in then above claims, and is by a different inventive entity. See col. 1 lines 58-64, col. 2 lines 9-13 and 32-56.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

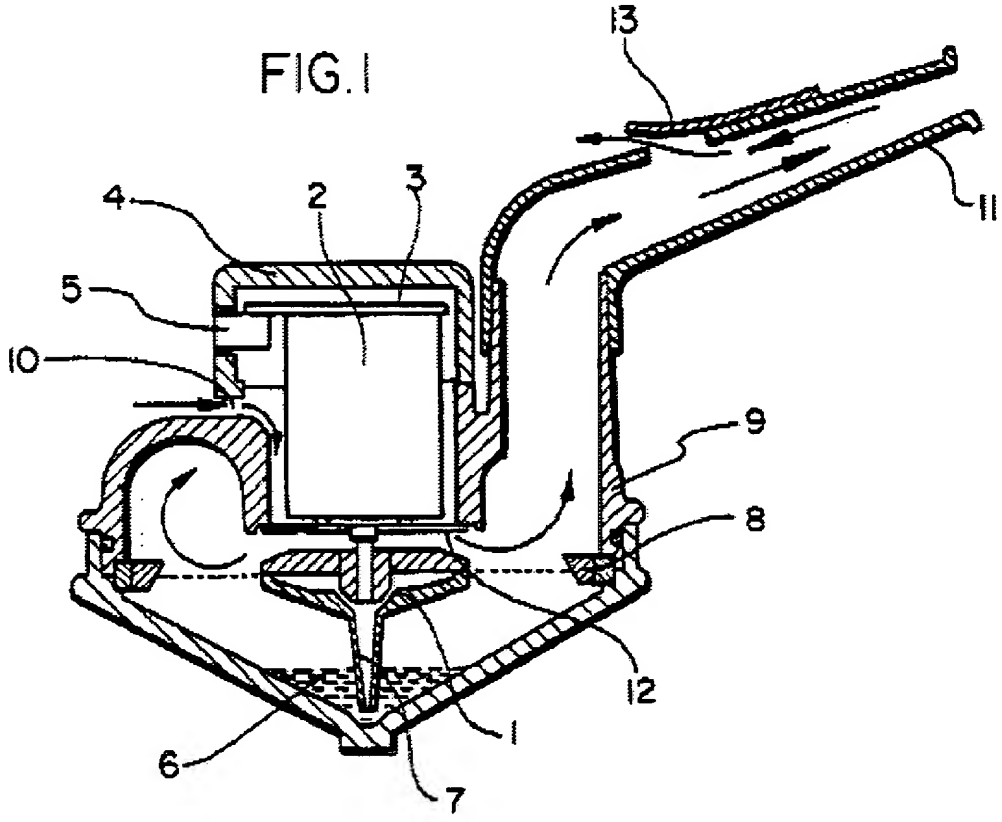
Claims 14,16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland-5782232 in view of Salter, et al.-WO 00/27455.

Rowland discloses a device having a mouthpiece having a first port, a 2nd port open to atmosphere closed by a one way flap valve 13; and a 3rd port. A medication dispenser is attached to the 3rd port.

However, the valve seat is not disclosed. Salter discloses a mouthpiece having an exhalation port with a flap valve and a grid valve seat. It would have been obvious to have

provided Rowland with a grid shaped valve seat for the flap valve, as this prevents undesirable internal deflection of the valve during inhalation. It also would have been obvious to have attached the end of the flap valve to the mouthpiece by a pin, instead of the apparent adhesive or welding, as merely being an obvious design choice. The applicant did not state why the pin connection was critical, solved a problem or was for a particular purpose, and the examiner contends that the prior art connection would have performed equally as well, as it also allows for the pivoting motion of the flap valve relative to the mouthpiece.

FIG. 1



Claims 15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salter, et al.-'234 in view of Salter, et al.-'455.

Salter discloses the invention as claimed with the exception of the filter and the valve being plastic. Salter discloses placing an exhalation filter in the exhalation port. It would have been obvious to have placed a filter in port 16 so as to prevent contaminants from entering the atmosphere. To use plastic for the flap valve would have been obvious as the application has not disclosed any criticality for the valve being plastic, not stated any problem which plastic solves, or for what purpose plastic is used and the examiner contends that the prior art material would work equally as well as the applicants as it is able to properly flex to open during exhalation and close against the valve seat when inhaling.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salter, et al.-'455 .

Salter discloses the invention as claimed with the exception of the filter in the 3rd port and the valve being plastic. As Salter discloses the placement of the filters in various locations, it would have been obvious to have placed one if the 3rd port to remove any contaminants from contaminating the discharge orifice of the medicator and to assist in the absorbing of any excess contaminants floating around in the interior of the device. To use plastic for the flap valve would have been obvious as the application has not disclosed any criticality for the valve being plastic, not stated any problem which plastic solves, or for what purpose plastic is used and the examiner contends that the prior art material would work equally as well as the applicants as it is able to properly flex to open during exhalation and close against the valve seat when inhaling.

Claims 12-14,17,18,21 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watt-'571 in view of Salter, et al.-'455.

Watt discloses the invention as claimed with the exception of the valve seat, the exhalation filters and that one end of the adaptor would be rigid and the other flexible.

Salter discloses the use of an exhalation filter and a valve seat for the exhalation flap valve. It would have been obvious to have provided the valve seat in order to prevent internal flexing of the valve flap during inhalation. It would have been obvious to have provided an exhalation filter to prevent the passage of dangerous gases to the ambient environment. It would have been obvious to have provided a rigid connector end on the adaptor already disclosed as having a flexible stretchable connector end, because as disclosed providing a connector for the adaptor with different ends for attaching to different medicators was known, and since the prior art is full of rigid connectors for connecting to a medicator, it would have been obvious to provide a rigid end of the connector having a flexible connector end, in order to provide maximum adaptability of a single connector allowing its connection to both medicators needing a flexible connection and medicators needing a rigid connection.

Claims 13,14,17,18,25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piper, et al.-'920 in view of Salter, et al.-'455.

Piper discloses the invention as claimed with the exception of the flange, the valve seat and the filter. It would have been obvious to have provided a flange on the connector attaching to tube 12, as an internal flange is necessary to achieve a proper gas-tight seal inside the connector. Salter teaches the valve seat and filters. It would have been obvious to have provided the valve seat in order to prevent internal flexing of the valve during inhalation. It would have been

obvious to have provided an exhalation filter in the 3d port to prevent the passage of dangerous gases to the ambient environment, and to remove any contaminants from contaminating the discharge orifice of the medicator and to assist in the absorbing of any excess contaminants floating around in the interior of the device.

Response to Arguments

Adaptor 20 of Esbenshade could be removed from tubes 21 and nebulizer 11, the bottom of the adaptor which used to be connected to tube 1 could be attached to 15 by a suitable inter adaptor and the top end previously attached to nebulizer 11 could be attached to an MDI.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Glenn K Dawson

Primary Examiner
Art Unit 3731

Gkd
18 January 2005